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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,722	04/19/2000	DAVID J SQUIRRELL	BJS-1498-130	3335
23117 7590 06/11/2007 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203				
			EXAMINER STEADMAN, DAVID J	
			ART UNIT 1656	PAPER NUMBER
			MAIL DATE 06/11/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	09/529,722		SQUIRRELL ET AL.	
	Examiner		Art Unit	
	David J. Steadman		1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 107-146 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 107-146 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/23/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

- [1]** Claims 107-146 are pending in the application.
- [2]** Applicant's amendment to the claims, filed on 2/23/07, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.
- [3]** Applicant's amendment to the specification, filed on 2/23/07, is acknowledged.
- [4]** Receipt of a sequence listing in computer readable form (CRF), a paper copy thereof, a statement that the sequence listing in computer readable form is the same as that of the paper copy, a statement that no new matter has been added to the specification by the paper copy of the sequence CRF, and an amendment directing entry of the sequence listing into the specification, all filed on 2/23/07, is acknowledged.
- [5]** Receipt of an information disclosure statement, filed on 2/23/07, is acknowledged.
- [6]** Applicant's arguments filed on 2/23/07 in response to the Office action mailed on 10/23/06 are acknowledged. Applicant's arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.
- [7]** The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.
- [8]** In a telephone message left with applicant's representative, B. J. Sadoff, the examiner acknowledged a discrepancy in the status of the Office action mailed on

Art Unit: 1656

10/23/06 as indicating the Office action is both a non-final and a final Office action. In the telephone message, the examiner acknowledged the 10/23/06 Office action is a non-final Office action.

Specification/Informalities

[9] The amendment filed on 2/23/07 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The sequences of SEQ ID NO:1-5 in the sequence listing filed on 2/23/07 and the amendment to the specification, filed on 2/23/07, to incorporate reference to these sequences (see particularly p. 3 of the amendment filed on 2/23/07). Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objection(s)

[10] Claim 144 is objected to in the recitation of "enzymaticall" as being the apparent misspelling of "enzymatically." Appropriate correction is required.

[11] Claim 146 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim shall refer to such other claims in the alternative only. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112, Second Paragraph

[12] The rejection of claims 108-109, 111, 115-116, 120-135 as being indefinite in the recitation of "Photinus pyralis luciferase which has a mutation at position 354," "Luciola luciferase with a mutation at position 354," "Luciola luciferase in which the amino acid at the 217 position," and "amino acid 87 or 107 in the sequence of *E. coli* adenylate kinase" is maintained for the reasons of record and the reasons stated below. Newly added claims 143 and 146 are included in the instant rejection as failing to clarify the reference sequence of the recited luciferase polypeptide in claims 123 and 133, respectively. Thus, claims 108-109, 111, 115-116, 120-135, 143, and 146 are rejected.

RESPONSE TO ARGUMENT: Applicant argues a reference sequence is not required for a skilled artisan to understand the metes and bounds of the claimed methods and products. Applicant refers to the CAFC's holding in *Capon v. Eshhar v. Dudas*, Appeal No. 03-1480, -1481, Fed. Cir. (August 12, 2005). Applicant further argues that the sequence of GenBank Accession No. BAA14303, having an N-terminal deletion, does not describe *E. coli* adenylate kinase.

Applicant's argument is not found persuasive. The examiner maintains the position that a skilled artisan recognizes that identifying a specific amino acid by position number depends upon the reference sequence. Put another way, the numbering of an amino acid position within a polypeptide sequence is relative to the intended reference sequence. While applicant disputes the examiner's assertion that GenBank Accession No. BAA14303 discloses an *E. coli* adenylate kinase polypeptide because the polypeptide has an N-terminal deletion, the reference nonetheless lists the organism of the sequence as *Escherichia coli* and the name of the protein as adenylate

Art Unit: 1656

kinase (see p. 1, bottom), such that a skilled artisan would recognize this polypeptide as being an *E. coli* adenylate kinase, albeit a truncated version. In this case, there is no recited limitation of the "*Photinus pyralis* luciferase which has a mutation at position 354," "*Luciola* luciferase with a mutation at position 354," "*Luciola* luciferase in which the amino acid at the 217 position," and "amino acid 87 or 107 in the sequence of *E. coli* adenylate kinase" such that the polypeptide has any particular sequence. As such, the claims are interpreted as encompassing any polypeptide that is recognized in the prior art as being a "*Photinus pyralis* luciferase," a "*Luciola* luciferase" or an "*E. coli* adenylate kinase." As demonstrated by applicant's disclosure of the sequences of GenBank Accession Nos. P69441 and BAA14303 (instant remarks at p. 21, top), each of these sequences has a different amino acid at their respective positions 87 and 107. As such, a skilled artisan would recognize that identification of a particular amino acid in the sequence of a polypeptide is dependent upon a specific reference sequence. Because the sequence of a polypeptide referred to as, e.g., "*E. coli* adenylate kinase," varies in the prior art, the terms "*Photinus pyralis* luciferase which has a mutation at position 354," "*Luciola* luciferase with a mutation at position 354," "*Luciola* luciferase in which the amino acid at the 217 position," and "amino acid 87 or 107 in the sequence of *E. coli* adenylate kinase" are indefinite.

Claim Rejections - 35 USC § 112, First Paragraph

[13] The new matter rejection of claims 117-119, 125-127, and 133-135 under 35 U.S.C. 112, first paragraph, is withdrawn upon further consideration and in view of applicant's showing of support for the recited limitations.

[14] The new matter rejection of claims 108-109, 115-116, and 120-135 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below. The rejection was fully explained in a prior Office action. Newly added claims 136-137 and 139-146.

RESPONSE TO ARGUMENT: Applicant argues specific support for the recitation of a *Luciola* luciferase with mutation at position 356 can be found at p. 8, lines 19-22 of the specification, which references European Application No. 92110808.0 and WO 95/25798.

Applicant's argument is not found persuasive. The cited disclosure of the instant specification fails to provide descriptive support for the limitations of "*Photinus pyralis* luciferase which has a mutation at position 354," "*Luciola* luciferase with a mutation at position 356," and "*Luciola* luciferase in which the amino acid at the 217 position is mutated to a hydrophobic amino acid." As noted in the prior Office action, the examiner acknowledges the specification's reference to European Application No. 92110808.0 (specification at p. 8, line 21). The examiner further acknowledges the specification's reference to WO 95/25798 at p. 8, line 21.

According to MPEP § 608.01(p).I, “[m]ere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973).”

According to the same section of the MPEP, incorporation by reference of material in a non-patent document “must be set forth in the specification and must: (1) Express a clear intent to incorporate by reference by using the root words “incorporat(e)” and “reference” (e.g., “incorporate by reference”); and (2) Clearly identify the referenced patent, application, or publication.” See 37 § 1.57(b). MPEP § 608.01(p) further states, “[i]f a reference to a document does not clearly indicate an intended incorporation by reference, examination will proceed as if no incorporation by reference statement has been made and the Office will not expend resources trying to determine if an incorporation by reference was intended.” It is noted that there is no clear intent to incorporate by reference material from European Application No. 92110808.0 using the root words “incorporat(e)” and “reference” (e.g., “incorporate by reference”). Thus, according to MPEP § 608.01(p), “examination will proceed as if no incorporation by reference statement has been made.”

As such, the examiner considers the noted limitations to introduce new matter.

[15] Claims 136-146 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

MPEP § 2163 states, "when filing an amendment an applicant should show support in the original disclosure for new or amended claims" and "[i]f the originally filed disclosure does not provide support for each claim limitation, or if an element which applicant describes as essential or critical is not claimed, a new or amended claim must be rejected under 35 U.S.C. 112, para. 1, as lacking adequate written description."

The claims recite the limitations of "*Photinus pyralis* luciferase sequence (SEQ ID NO:1)," "*L. cruciata* luciferase (SEQ ID NO: 2)," "*L. lateralis* luciferase (SEQ ID NO: 3)," "*L. mingrelica* luciferase (SEQ ID NO: 4)," and "*E. coli* adenylate kinase (SEQ ID NO:5)." According to applicant, the added claims are supported by "the state of knowledge of the art as wild-type sequences" (instant remarks at p. 19, top).

According to MPEP § 608.01(p).I, "[m]ere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. *In re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973)."

According to the same section of the MPEP, incorporation by reference of material in a non-patent document "must be set forth in the specification and must: (1) Express a clear intent to incorporate by reference by using the root words "incorporat(e)" and "reference" (e.g., "incorporate by reference"); and (2) Clearly identify the referenced patent, application, or publication." See 37 § 1.57(b). MPEP § 608.01(p) further states, "[i]f a reference to a document does not clearly indicate an intended incorporation by

Art Unit: 1656

reference, examination will proceed as if no incorporation by reference statement has been made and the Office will not expend resources trying to determine if an incorporation by reference was intended." It is noted that there is no clear intent to incorporate by reference material from European Application No. 92110808.0 using the root words "incorporat(e)" and "reference" (e.g., "incorporate by reference"). Thus, according to MPEP § 608.01(p), "examination will proceed as if no incorporation by reference statement has been made."

As such, the examiner considers the noted limitations to introduce new matter.

[16] The written description rejection of claims 107-135 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below. The rejection was fully explained in a prior Office action. Newly added claims 136-146 are included in the instant rejection. Thus, claims 107-146 are rejected.

RESPONSE TO ARGUMENT: Applicant argues that in view of the prior art of record, one of skill in the art will appreciate that luciferases and adenylate kinases share a common related structure as well as function.

Applicant's argument is not found persuasive. The examiner maintains the position that the genus of mutant luciferase and mutant adenylate kinases are not adequately described in the specification. In this case, each genus of luciferase and adenylate kinase polypeptides and corresponding encoding nucleic acids as recited in the claims are not so limited to those of the prior art and there is no requirement in the claims that the structures of the mutant luciferase and/or adenylate kinase

Art Unit: 1656

polypeptide(s) maintain a common structural element or common structural features. Instead, each genus, with the exception of a single amino acid substitution in certain of the claims, is not limited to having any common structural feature(s). Thus, regardless of whether the un-modified, *i.e.*, wild-type, luciferase and/or adenylate kinase polypeptide(s) are highly conserved, this provides no indication as to whether the resulting mutant luciferase and/or adenylate kinase polypeptide(s) will maintain a common structural element or common structural features. In this case, the luciferase species disclosed in European Patent Application No. 92 1 10808.0 and WO 95/25798 and adenylate kinase species disclosed by Liang et al. and Gilles et al. fail to reflect the structural variation among the members of the genus, which encompasses species that are widely variant with respect to their structures, particularly as the claims recite the limitations of "has a mutation" or "comprises a mutation," which have been interpreted in accordance with MPEP 2111.03 as encompassing any other mutations within the recited luciferase and/or adenylate kinase polypeptide.

Given the lack of description of a representative number of species, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

[17] The scope of enablement rejection of claims 107-135 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below. The

Art Unit: 1656

rejection was fully explained in a prior Office action. Newly added claims 136-146 are included in the instant rejection. Thus, claims 107-146 are rejected.

RESPONSE TO ARGUMENT: Applicant argues a skilled artisan would not be required to alter every amino acid to make and use the claimed invention. According to applicant, the CAFC's holding in *Capon v. Eshhar v. Dudas*, Appeal No. 03-1480, - 1481, Fed. Cir. (August 12, 2005) is analogous to the instant situation.

The examiner maintains the position that the specification, even in view of the teachings of the prior art, fails to enable the full scope of the claimed invention without requiring undue experimentation. According to applicant, it appears that the specification, in view of the teachings of the prior art, would enable a skilled artisan to make any thermostable luciferase polypeptide/encoding nucleic acid as encompassed by the claims. The claims are so broad as to essentially encompass the use of any mutant luciferase or adenylate kinase that has the required activity as recited in the claims. While applicant argues that a skilled artisan is required to make only "some" variations within the sequence, it is noted that the claims encompass any amino acid mutation(s) and the specification should enable the full scope of the claim, not just those variants having "some" amino acid alterations, which applicant argues are enabled by the specification. However, neither the specification nor the prior art nor the combination thereof provides the necessary guidance to make all luciferase and adenylate kinase variants as encompassed by the claims and there was a high level of unpredictability in the art in altering the amino acid sequence of a protein to achieve a desired activity, which is undisputed by applicant. While the examiner acknowledges that the

Art Unit: 1656

specification and prior art disclose screening methods for determining whether the mutant luciferase or mutant adenylate kinase polypeptides are useful in accordance with the claimed invention, it was not routine in the art at the time of the invention to make all luciferase and adenylate kinase variants, having essentially any alterations that achieve the desired activity/utility as broadly encompassed by the claims.

Given the broad scope of the claims, the lack of guidance and working examples, the high level of unpredictability in the art, and the amount of experimentation, undue experimentation would be required for a skilled artisan to make the full scope of the claimed invention.

Applicant's reliance on *Capon v. Eshhar v. Dudas* is acknowledged, however, it is the examiner's position that the facts of *Capon* are not analogous to the instant case. In *Capon*, the nucleotide sequences of the chimeric genes were *known in the prior art*. In other words, the chimeric genes were a combination of *known* nucleotide sequences. Contrary to *Capon*, the claims of the instant case are not so limited to the use of mutant luciferase and/or mutant adenylate kinase polypeptide(s) that were known in the prior art at the time of the invention. Instead, the claims encompass the use of any mutant luciferase and/or mutant adenylate kinase polypeptide(s), including those that are not recognized in the prior art of record and, for reasons set forth above, it would require undue experimentation for a skilled artisan to make every possible luciferase and/or adenylate kinase variant as encompassed by the claims.

Claim Rejections - 35 USC § 103

Art Unit: 1656

[18] The rejection of claims 107-108, 110-115, and 120-124 under 35 U.S.C. 103(a) as being unpatentable over Backman et al., Squirrell (1), Squirrell (2), and Gilles et al. is maintained for the reasons of record and the reasons stated below. The rejection was fully explained in a prior Office action. Newly added claims 136, 138-139, and 141-142 are included in the instant rejection as corresponding to claims 108, 111, 115, 120, and 123 and further including the recitation of specific sequence identifiers. Thus, claims 136, 138-139, and 141-142 are rejected.

RESPONSE TO ARGUMENT: Applicant reiterates arguments from the prior response, arguing the examiner has combined the references through an inappropriate use of hindsight, asserting the examiner's assertion of where motivation exists is circular, *i.e.*, because the prior art documents can be combined, there was motivation to do so. According to applicant, one of ordinary skill in the art would have no motivation to combine the cited references to arrive at the claimed invention.

Applicants' argument is not found persuasive. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Contrary to applicant's assertion, the examiner's assertion of where motivation can be found is not circular as there is clear motivation from the references themselves. At the time of the invention, as noted in the prior Office action, the use of elevated temperature to purify luciferase from adenylate kinase activity was well-known in the art as evidenced by Squirrell et al. (1). As noted in the prior Office action, the reference of Squirrell et al. (1) suggests the use of elevated ambient temperature to inactivate adenylate kinase activity in a preparation of luciferase. However, Squirrell et al. (2) notes that "[t]he heat stability, of wild and recombinant type luciferases is such that they lose activity quite rapidly when exposed to temperatures in excess of about 30°C, particularly over 35°C, and this renders the enzyme deficient when used at high ambient temperatures" (p. 1, fourth full paragraph). The reference of Backman et al. provides an alternative concept for inactivating an undesired protein from another, *i.e.*, recombinantly expressing a thermostable enzyme in a mesophilic host and heat treating the resulting protein to remove a contaminating activity. Squirrell et al. (2) teaches such thermostable luciferase enzymes and Gilles et al. teaches such a mesophilic *E. coli* host with the added advantage of expressing a thermolabile adenylate kinase. At the time of the invention, one would have been motivated to apply the method of Backman et al. in combination with the method of Squirrell et al. (1) in order to prevent heat inactivation of luciferase. One of ordinary skill in the art would have been motivated to use the mesophilic host of Gilles et al. in the method of Backman et al. in order to ensure deactivation of adenylate kinase activity during heat treatment of the thermostable luciferase.

[19] The rejection of claims 117-119 and 125-127 under 35 U.S.C. 103(a) as being unpatentable over Backman et al. in view of Squirrell (1), Squirrell (2), and Gilles et al. as applied to claims 107-108, 110-115, and 120-124 above, and further in view of Novagen 1997 Catalog and Kiel et al. is maintained for the reasons of record and the reasons stated below. The rejection was fully explained in a prior Office action. Newly added claim 143 is included in the instant rejection as corresponding to claim 125 and further including the recitation of a specific sequence identifier. Thus, claims 117-119, 125-127, and 143 are rejected.

RESPONSE TO ARGUMENT: Applicant appears to rely on the arguments set forth above in traversing the instant rejection. However, as the prior art provides a clear motivation for combining the references for the reasons of record and reasons noted above, it is the examiner's position that the claimed invention would have been obvious at the time of the invention.

[20] The rejection of claims 107, 109-114, 116, and 128-132 under 35 U.S.C. 103(a) as being unpatentable over Backman et al. in view of Squirrell (1), Kajiyama et al., and Gilles et al. is maintained for the reasons of record and the reasons stated below. The rejection was fully explained in a prior Office action. Newly added claims 137, 140, and 144-145 are included in the instant rejection as corresponding to claims 109, 116, 128, and 131 and further including the recitation of specific sequence identifiers. Thus, claims 107, 109-114, 116, 128-132, 137, 140, and 144-145 are rejected.

Art Unit: 1656

RESPONSE TO ARGUMENT: Applicant appears to rely on the arguments set forth above in traversing the instant rejection. However, as the prior art provides a clear motivation for combining the references for the reasons of record and reasons noted above, it is the examiner's position that the claimed invention would have been obvious at the time of the invention.

[21] The rejection of claims 117-119 and 133-135 under 35 U.S.C. 103(a) as being unpatentable over Backman et al. in view of Squirrell (1), Kajiyama et al., and Gilles et al. as applied to claims 107, 109-114, 116, and 128-132 above, and further in view of Novagen 1997 Catalog and Kiel et al. is maintained for the reasons of record and the reasons stated above. The rejection was fully explained in a prior Office action. Newly added claim 146 is included in the instant rejection as corresponding to claim 133 and further including the recitation of a specific sequence identifier. Thus, claims 117-119, 133-135, and 146 are rejected.

RESPONSE TO ARGUMENT: Applicant appears to rely on the arguments set forth above in traversing the instant rejection. However, as the prior art provides a clear motivation for combining the references for the reasons of record and reasons noted above, it is the examiner's position that the claimed invention would have been obvious at the time of the invention.

Conclusion

[22] Status of the claims:

Art Unit: 1656

Claims 107-146 are pending.

Claims 107-146 are rejected.

No claim is in condition for allowance.


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656